Remarks/Arguments

In response to the Office Action mailed October 20, 2004, Applicants respectfully request that the Examiner reconsider the rejections of the remaining claims.

Claims 1, 3-8 and 10-19 remain.

Rejection under 35 U.S.C. § 103(a) over *Schinitsky, et al.* in view of *Murad, Herstein* and *Taylor.*

Claims 1, 3-8 and 10-19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Schinitsky, et al.* (U.S. Patent 4,938,969) (hereinafter "the *Schinitsky* reference'), in view of *Murad* (U.S. Patent 5,804,594) (hereinafter "the *Murad* reference"), *Herstein* (U.S. Patent 5,902,591) (hereinafter "the *Herstein* reference") and *Taylor* (U.S. Patent 5,308,621) (hereinafter "the *Taylor* reference). *See* Office Action, page 2.

The combination of the teachings of the *Schinitsky, Murad, Herstein* and *Taylor* references fails to render the present invention obvious. To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants' disclosure. See MPEP § 2143. *See also In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991).

Specifically, the references do not render obvious a stable solution of at least 5% ascorbic acid at a pH of 3.5 to 4.1 without the presence of an organoclay. The *Herstein* reference discloses a stable solution comprising ascorbic acid at a pH of 3.5 to 4.1 in the presence of an organoclay. *Herstein* teaches away from a stable solution without an organoclay. Column 13, lines 37-39 of *Herstein* state "[w]ithout the organoclay ingredient, the emulsion would begin to

break down after a few days, i.e., 2-3 days." Column 1, lines 8-11 state "[m]ore particularly, the invention relates to topical emulsion compositions containing ascorbic acid (vitamin C) which are stabilized by means of certain clay/cationic surfactant combinations." Column 2, lines 53-60 state "[i]t has now been discovered that a new, stable topical emulsion composition containing ascorbic acid, preferably from about 0.1 to 20 wt. %, more preferably about 2 to 10 wt. % and more particularly form about 4% to about 8% ascorbic acid based on the weight of the final composition can be obtained by using the ascorbic acid in combination with an emulsion composition containing a stabilizing effective amount of an organoclay composition." The present invention does not include an organoclay yet does not expand or lose integrity on storage (page 4, lines 24-25). The Examiner states that Applicant's own Specification discloses the use of amine salts on pages 8 and 9 of the Specification. Applicant respectfully notes that the amine salts are part of possible formulations of the ascorbic acid and tyrosine compound components. Page 8, lines 30-32 of the Specification state "[t]he ascorbic acid and tyrosine compound components of the present compositions may be formulated in part or whole in a neutralized or salt form. Acceptable amine salts include..." The organoclay of *Herstein* is not part of a formulation of an ascorbic acid or tyrosine compound. The organoclay of *Herstein* is an additive to the emulsion as opposed to a salt form of ascorbic acid or tyrosine.

The Examiner has stated that *Taylor* reference does not exclude the use of solubilized ascorbic acid. While *Taylor* does not exclude the use of solubilized ascorbic acid, the mechanism used by *Taylor* teaches away from the use of solubilized ascorbic acid. Column 1, lines 36-40 state "[s]urprisingly we have found that an effective composition of ascorbic acid is provided using a pharmaceutically acceptable carrier without the need to dissolve the available ascorbic acid if the ascorbic acid is present in the form of fine particles."

Applicant respectfully reiterates the definition of pH, as found in Hawley's Condensed Chemical Dictionary:

pH is a value taken to represent the acidity of an aqueous solution, it is defined as the logarithm of the reciprocal of the hydrogen-ion concentration of a solution:

pH = log10(1/[H+])

See Hawley's Condensed Chemical Dictionary, Eleventh Ed., I. Sax and R. Lewis, Eds., Van Nostrand Reinhold Co., New York, 1987, page 893. One can see that, as defined above, to possess pH, a composition must be first be a solution, and that such a solution be aqueous, i.e., water-based. *Murad*, *Herstein* and *Taylor* do not properly describe aqueous solutions of ascorbic acid, and therefore cannot possess pH. Not only does *Murad* not disclose pH, *Murad's* preferred route of administration is oral and the Examples are directed to non-aqueous methods of oral administration. *See* Column 10, lines 1-65.

The *Schinitsky*, *Murad* and *Taylor* references do not disclose the pH of the compounds within each reference and therefore do not disclose all limitations of the present invention. As at least one of the three basic criteria is not met, a prima facie case of obviousness is not established.

Rejection under 35 U.S.C. § 103(a) over *Schinitsky, et al.* in view of *Murad*, *Darr* and *Taylor*.

Claims 1, 3-8 and 10-19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Schinitsky, et al.* (U.S. Patent 4,938,969) (hereinafter "the *Schinitsky* reference'), in view of *Murad* (U.S. Patent 5,804,594) (hereinafter "the *Murad* reference"), *Darr* (U.S. Patent 5,140,043) (hereinafter "the *Darr* reference") and *Taylor* (U.S. Patent 5,308,621) (hereinafter "the *Taylor* reference). *See* Office Action, page 7.

The combination of the teachings of the *Schinitsky, Murad, Darr* and *Taylor* references fails to render the present invention obvious. The *Darr* reference teaches away from the use of a solution of ascorbic acid at a pH 3.5 to 4.1. Column 1, lines 6-11 of *Darr* state "[m]ore particularly, it relates to topical compositions containing L-ascorbic acid (vitamin C) which are stabilized in aqueous solutions by providing a concentration of L-ascorbic acid above about 1% (w/v) and maintaining the pH below about 3.5." Column 3, lines 29-32 state "...the pH of the composition is no more than about 3 to 3.5, preferably no more that about 2.5."

Applicant respectfully reiterates the definition of pH, as found in Hawley's Condensed Chemical Dictionary:

pH is a value taken to represent the acidity of an aqueous solution, it is defined as the logarithm of the reciprocal of the hydrogen-ion concentration of a solution:

$$pH = \log10(1/[H+])$$

See Hawley's Condensed Chemical Dictionary, Eleventh Ed., I. Sax and R. Lewis, Eds., Van Nostrand Reinhold Co., New York, 1987, page 893. One can see that, as defined above, to possess pH, a composition must be first be a solution, and that such a solution be aqueous, i.e., water-based.

The *Schinitsky*, *Murad* and *Taylor* references do not disclose the pH of the compounds within each reference and therefore do not disclose all limitations of the present invention. As at least one of the three basic criteria is not met, a prima facie case of obviousness is not established.

No new matter has been added. Applicants respectfully submit that the Claims as they now stand are patentably distinct over the art cited during the prosecution thereof.

With the addition of no new claims, no additional filing fees are due. The Director is hereby authorized to charge any fees or credit any overpayment to Deposit Account Number 23-2426 of WINSTEAD SECHREST & MINICK P.C (referencing number 41758-P001P2X1).

If the Examiner has any questions or comments concerning this paper or the present application in general, the Examiner is invited to call the undersigned at 214-745-5633.

Respectfully submitted,
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Date: January 20, 2005

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